K090378

510 (k) Summary

FEB 23 2009

Submitter: BERCHTOLD Holding GmbH
Ludwigstaler Straße 125
D- 78532 Tuttlingen
Germany

Contact Person: Silke Goral
Regulatory Affairs
Phone: 0049 7461 181-155
Fax: 0049 7461 181-8155
Silke.Goral@BERCHTOLD.biz

Preparation Date: February 06, 2009

Trade Name: CHROMOPHARE® E 668

Common Name: Surgical lamp

Classification Name: Light, Surgical, Ceiling mounted

Predicate Device: BERCHTOLD CHROMOPHARE® E 558 (K083066)

Device Description: The new BERCHTOLD CHROMOPHARE® E 668 surgical light is suitable for all types of surgical procedures. With the use of Light Emitting Diodes (LEDs) in this light, BERCHTOLD realizes high illumination intensity with a lower heat radiation and less pattern variation compared to previous generations of BERCHTOLD products. The light features easy-to-operate swivel arms. Each light functions with an optional integrated CCD video camera and/or with upward "EndoLite" and/or with downward "GuideLite" for endoscopic procedures. The lights could be combined among each other.

Intended Use of the device: The CHROMOPHARE® E 668 is intended to be used to provide visible illumination to the surgical field of the patient.

Indications for Use: The surgical lights BERCHTOLD CHROMOPHARE® E 668 is intended to illuminate locally the operating site on the patient's body with a high intensity, shadow free, "cold" light.

Summary of technological characteristics compared to the predicate device:

The BERCHTOLD CHROMOPHARE® E 668 is substantially equivalent to the surgical light BERCHTOLD CHROMOPHARE® E 558 (K083066). Similarities and differences are tabulated below. Any differences between the CHROMOPHARE E 668 and the predicate device do not alter the safety or efficacy of the device.

	Legally marketed device CHROMOPHARE® E 558	**New device CHROMOPHARE® E 668**
Intended use	Illumination of the operating site on a patient's body	Same
Input power	120V, 1- phase lines, 60Hz	Same
Protection against electrical shock	Class I	Same
Diameter of light body	568mm	638mm ✓
Diameter of reflectors	36 reflectors: 35mm 36 reflectors: 40mm	48 reflectors: 35mm 48 reflectors: 40mm ✓
Lamp technology	Light Emitting Diode	Same
Reflector	72 individual reflectors	96 individual reflectors ✓
Power consumption of bulb	<2,5W each	Same
Light / heat filter technology incl. UV light filter mechanism	None	None
Color rendering Index R_a	94	Same
Color temperature	3600K, 4000K, 4500K, 5000K	Same
Central illuminance (at 1m)	70000 – 140000lux	80000 - 160000
Light field diameter	140 – 285mm	150 – 290mm
Depth of illumination	805mm	850mm
Total irradiance E_e	442 W/m²	600 W/m²
UV- irradiance (≤400nm)	0 W/m²	Same
Light focusing mechanism	Pressure Sensitive Handgrip	Same
Life time of bulb	20000h	Same
Reusable steam sterilizable lamp handle	Yes	Same
Additional light controls in separate wall box	Standard	Same
Ambient illumination for minimally invasive surgeries	Optional upward "EndoLite" and/or downward "GuideLite"	Same
CCD video camera located in sterilizable lamp handle	Optional feature	Same

Performance Summary:

This device conforms to IEC 60601-2-41:2001 specifications for performance of surgical lamps. This device conforms to IEC 60601-1 and IEC 60601-1-2 for electrical safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Berchtold GmbH & Co.
% Underwriters Laboratories, Inc.
Mr. Jeff D. Rongero
12 Laboratory Drive
Research Triangle Park, North Carolina 27709

FEB 23 2009

Re: K090378
Trade/Device Name: CHROMOPHARE® E 668
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: II
Product Code: FSY
Dated: February 13, 2009
Received: February 17, 2009

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

2/20/05

Enclosure

Indications for Use

510(k) Number (if known):

Device Name:

CHROMOPHARE® E 668

Indications for Use:

The surgical light BERCHTOLD CHROMOPHARE® E 668 is intended to illuminate locally the operating site on the patient's body with a high intensity, shadow free, "cold" light.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K090378